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PATENT

Money Docket No.: A-67616-2/RMS/DCF/SRN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

STUELPNAGEL et al.

Serial No. 09/636,387

Filed: August 9, 2000

For: *Automated Information Processing in
Randomly Ordered Arrays*

) Examiner: B.J. Forman

) Group Art Unit: 1655

CERTIFICATE OF MAILING

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on January 31, 2002

Signed: Maria Ciganovich

Maria Ciganovich

RESPONSE TO OFFICE ACTION

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

This is in response to the Office Action mailed September 3, 2001, for the above-identified U.S. patent application. This response is timely filed on or before the extended due date of February 3, 2002, the time period for response being extended by the attached petition for 2-month extension and requisite fee in accordance with 37 CFR § 1.17(a)(3).

The Assistant Commissioner is hereby authorized to charge any additional fees, including extension of time fees or other relief as may be required, or credit any overpayment to Deposit Account No. 06-1300 (Our File A-67616-2/RMS/DCF/SRN).

AMENDMENTS

In the Claims

Please amend the claims as follows:

49. (Amended) A method of determining the presence of a target analyte in a sample comprising:

a) acquiring a first data image of a random array composition comprising:

- i) a substrate with a surface comprising discrete sites;
- ii) a population of microspheres comprising at least a first and a second subpopulation each comprising a bioactive agent; and
- iii) a fiducial,

wherein said microspheres are randomly distributed on said surface such that said discrete sites contain microspheres;

b) using said fiducial to register said first data image to create a registered first data image;

c) contacting said random array composition with said sample;

d) acquiring a second data image from said array with said sample;

e) using said fiducial to register said second data image to create a registered second data image; and

f) comparing said first and said second registered data images to determine the presence or absence of said target analyte.

61. (Amended) A method of determining the presence of a target analyte in a sample comprising:

a) providing a registered first data image of a random array composition comprising:

- i) a substrate with a surface comprising discrete sites;
- ii) a population of microspheres comprising at least a first and a second subpopulation each comprising a bioactive agent; and

~~(ii) a fiducial,~~

~~wherein said microspheres are randomly distributed on said surface such that said discrete sites contain microspheres;~~

~~b) contacting said random array composition with said sample;~~

~~c) acquiring a second data image from said array with said sample;~~

~~d) using said fiducial to register said second data image to create a registered second data image; and~~

~~e) comparing said first and said second registered data images to determine the presence or absence of said target analyte.~~

68. (Amended) The method according to claim 49 or 62, wherein each subpopulation comprises an identifier binding ligand that will bind a decoder binding ligand whereby the identification of the bioactive agent is elucidated.

REMARKS

Claims 49 through 54 and 61 through 75 are pending, and stand rejected.

Claims 49, 61, 68 and 69 are amended for technical clarity. A copy of the marked-up version of the amended claims is attached to the response as Appendix A, captioned "MARKED UP VERSION OF THE CLAIMS."

Appendix B is a copy of the current claims and is attached for the Examiner's convenience. Favorable consideration of the following comments relative to the outstanding rejections as they may apply to the present claims is respectfully requested for the following reasons.

Claim Objections

Appropriate corrections have been made to rectify the informalities in the claims 49, 61, and 68.

Rejection under 35 U.S.C. § 112 second paragraph

Claim 68 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants have amended claim 68 for technical clarity and in accordance with Examiner's suggestions. Accordingly, the Applicants submit that the claims fulfill the requirements of 35 U.S.C. 112 second paragraph, and the rejection should be withdrawn.

Rejection under 35 U.S.C. § 102(e) as anticipated by Walt et al.

Applicants respectfully traverse the rejection of claims 49, 53, 54, 61, 62 and 65-68 under 35 U.S.C. § 102 as anticipated by Walt et al. U.S. Patent No. 6,023,540.

Walt teaches a microsphere-based analytic chemistry system comprising a substrate with a surface comprising discrete sites and a population of microspheres with chemical functionalities wherein said microspheres are distributed on the surface of the substrate. Walt is silent with respect to teaching an array composition comprising fiducial alignment.

In contrast the present invention provides for array compositions that comprise a substrate with a surface comprising discrete sites; a population of microspheres comprising bioactive agents wherein said microspheres are distributed on the surface of the substrate, at least one fiducial and fiducial alignment. The fiducials are used to generate registered data images, and the comparison among the images can then lead to the identification and elucidation of the bioactive agent.

Examiner argues that the Walt *et al.* patent discloses a method of determining the presence of a target analyte comprising a substrate with discrete sites and a population of microspheres in the same manner as in the present invention.

Without agreeing with the Examiner's position, Applicants have amended Claims 49 and 61 to indicate that the method includes a step of "fiducial alignment." Support for this amendment can be found in the specification on page 7, lines 20-24 and elsewhere in the application. Thus, the rejection of record should be withdrawn.

The law is well established that in order to anticipate a claim, the prior art must disclose "each and every element" of the claimed invention. SSIH Equipment S.A. v. U.S. Inc. Int'l. Trade Commission, 218 USPQ 678, 688 (Fed. Cir. 1983). As stated by the Federal Circuit in In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990), "[f]or a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." (Emphasis added). See also Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc., 33 USPQ2d 1496 (Fed. Cir. 1995).

Here, each and every element is not present, since nowhere in the Walt patent is "fiducial alignment" mentioned. Accordingly, the reference does not anticipate the present claims, and the rejection is improper.

Rejection under 35 U.S.C. § 103(a) as obvious over Walt et al. in view of Augenlicht et al.

Applicants respectfully traverse the rejection of claims 50-52, 63-65 and 69-75 under 35 U.S.C. § 103 (a) as anticipated by Walt *et al.* U.S. Patent No. 6,023,540 in view of Augenlicht U.S. Patent No. 4,981,783, and in view of the definitions of Morris ed. (Dictionary of Science and Technology).

Examiner argues that the Walt and Augenlicht patents together teach all the limitations of the dependant claims of the present invention.

Walt has been described above.

Augenlicht teaches a method of determining the expression of individual cloned genes that are stored in a defined pattern on substrates such as nitrocellulose filters and teaches the uses of fiducial markings to identify the position of individual clones on the filter relative to the fiducial. Augenlicht does not teach or suggest the use of fiducial in an array comprising microspheres, which can be randomly arranged on a substrate.

Applicants note that there are three requirements to establish a *prima facie* case of obviousness. These include that "there must be some suggestion or motivation, either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." (MPEP § 2143).

Applicants respectfully remind the Examiner that it is legally and logically impossible for a dependant claim to be obvious when the claim from which it depends is non-obvious. Furthermore, in light of the amendments, the references do not teach or suggest all of the elements of the present invention. There is no step of fiducial alignment in either of the references.

In view of the above, Applicants submit that the claims are not obvious over Walt et al. in view of the knowledge available to one skilled in the art as illustrated in Augenlicht. Accordingly, Applicants respectfully request the Examiner to withdraw this rejection. Applicants submit that not all elements are met, because the present invention is not the same apparatus as the apparatus taught in the prior art.

CONCLUSION

Applicants submit that the claims are now in condition for allowance and an early notification of such is solicited. Please direct any calls in connection with this application to the undersigned at (415) 781-1989.

Respectfully submitted,

FLEHR HOHBACH TEST
ALBRITTON & HERBERT, LLP

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